DEC 15 2000 K003147

510(k) Summary
Laserscope's Lyra Surgical Laser System & Accessories

This 510(k) Summary of Safety & Effectiveness for the Laserscope's Lyra Surgical Laser System & Accessories is submitted in accordance with the requirements of SMDA 1990 and CFR 807.92 and CFR 807.93 follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant :	Laserscope
Address:	3052 Orchard Drive San Jose, CA 95134-2011
Contact Person:	Paul H. Hardiman Manager, Regulatory Affairs
Telephone:	(800) 243-9384 ext. 6795 (503) 961-1688 (FAX)
Date Summary Prepared:	September 29, 2000
Device Name:	Laserscope's Lyra Surgical Laser System & Accessories
Common Name:	Laser Instrument, Surgical Laser System and Accessories
Classification Name:	The Lyra Series Surgical Laser System has been specifically classified as a Class II medical device by the OB/GYN, General Plastic Surgery, and ENT Device Advisory Panels. Product Code: **GEX**.
Legally Marketed Predicate Devices:	The following clearances apply: Lyra Surgical Laser System And Accessories ORION Surgical Laser System Lyra Surgical Laser System And Accessories
Indications For Use:	The Lyra is intended for the removal of unwanted body hair which causes the condition known as *Pseudofolliculitis barbae* (PFB) (Shaving/Razor Bumps).
Clinical Data:	The Laserscope Lyra Series Surgical Laser System & Accessories were used in a clinical trial to demonstrate

safety and efficacy of this device for the specific indication for the lightening and removal of unwanted body hair in the treatment of *Pseudofolliculitis barbae* (Shaving/Razor bumps). Clinical data confirming the safety and efficacy of the laser system and delivery devices are included with this submission.

H. Performance Standards

The Lyra Series Surgical Laser System conforms with federal regulations and the performance standards 21 CFR 1040.10 and 1040.11 for medical laser systems.

I. Substantial Equivalence Statement

In the opinion of Laserscope: the Lyra Surgical Laser System and Accessories is substantially equivalent to the Orion Surgical Laser Systems and the Laserscope Lyra Laser System & Accessories both technologically and for the removal of unwanted hair; unwanted hair which results in the condition known as *Pseudofolliculitis barbae.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2000

Mr. Paul H. Hardiman
Manager, Regulatory Affairs
Laserscope
3052 Orchard Drive
San Jose, California 95134

Re: K003147
Trade Name: Lyra Series Surgical Laser System
Regulatory Class: II
Product Code: GEX
Dated: October 9, 2000
Received: October 10, 2000

Dear Mr. Hardiman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K003147

Device Name: LYRA SERIES SURGICAL LASER SYSTEM

Indications for Use:

The LYRA Series Surgical Laser System is intended for the removal of unwanted body hair which causes the condition known as Pseudofolliculitis barbae (PFB) (Shaving/Razor Bumps) in Fitzpatrick Skin Types I to VI.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ or Over The-Counter-Use

(per 21 CFR 801.109)

Mark N Milhauser

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K003147

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